

**REMARKS**

This responds to the Office Action mailed on July 17, 2006.

No claims are amended, canceled, or added.

**§103 Rejection of the Claims**

Claims 19-22, 24 and 34-42 were rejected under 35 U.S.C. § 103(a) as being unpatentable over US Patent No. 4,765,983 to Takayanagi et al. in view of US Patent No. 4,594,240 to Kawata et al.

Applicants traverse the rejection and request its withdrawal. A proper prima facie case of obviousness has not been made by the Examiner.

For establishment of a prima facie case of obviousness, the combination of the cited references must show all the features of the claimed invention. *In re Wilson*, 424 F.2d 1382, 1385 (C.C.P.A. 1970).

Claim 19, upon which all the pending claims ultimately depend, unequivocally recites that the device is water-erodable and comprises two layers, each of which are explicitly stated to be water-erodable.

Takayanagi does not disclose a tape that is soluble or erodable in water. Takayanagi makes clear that in the adhesive medical tape he discloses, the backing layer is NOT water-soluble or water-erodible. For example, it is stated (column 3, lines 50-68) that “[t]he support layer composed of such an intestine-soluble polymer functions to prevent the form of the adhesive medical tape from being collapse or deformed . . . the dissolution of such a portion scarcely occurs (i.e., the useless dissolution is very small).” The “intestine soluble” support layer, which backs the medicament-containing soluble layer, thus is not water-erodible. The medicament-containing soluble layer is stated (column 2, lines 58-61) as being a “water-soluble polymer” that is “capable of dissolving mainly in the oral cavity or stomach.” The backing layer of Takayanagi that is stated to dissolve in the intestine is clearly indicated to be swallowed by the patient after the water-soluble medicament-containing layer has dissolved, such that it may reach the intestine to be dissolved. In contrast, the backing layer of the instant claim 19 is indicated to

dissolve in the mouth such that no solid material from the pharmaceutical carrier device of the present invention is swallowed by the patient. Accordingly, that claim element of the instant claim 19 is not found in the disclosure of Takayanagi.

Kawata does not disclose an adhesive preparation that is erodable. Indeed, Kawata explicitly states that the preparation is NOT erodable. Referring to column 1, lines 4-15, Kawata states that the preparation “comprises a layer of a pharmaceutical composition containing a prostaglandin in the sheet-like form and a flexible base sheet, said agent being able to ... be retained on the gingiva *for a long period of time without being dissolved and disintegrated with saliva and hence without being swallowed*” (emphasis added). Referring to column 1, lines 63-68, Kawata states that “a preparation comprising a layer of a pharmaceutical composition ... and a flexible base sheet is suitable because it can be retained within the oral cavity *for a long period of time without being affected with saliva ...*” (emphasis added).

The allusion made by the Examiner to the statement of Kawata that water-soluble material such as gums and cellulose derivatives can be used refers ONLY to the “pharmaceutical composition” portion (column 2, lines 37-50). Please refer to column 2, lines 19-24, wherein it is stated that “the present invention comprises a sheet-like layer of a pharmaceutical composition containing a prostaglandin as the active ingredient in admixture with one or more high molecular weight compounds and a flexible base sheet.” Then at column 2, lines 41-50, it is stated that “[t]he water soluble high molecular weight compounds are classified into two groups; (1) those compounds having a low dissolution rate in water, such as ... karaya gum ... and (2) those compounds having a high dissolution rate in water, such as ... cellulose derivatives...” Clearly, these compounds are disclosed as being in the sheet-like layer of a pharmaceutical composition, NOT in the flexible base sheet, which is explicitly stated (column 2, lines 25-31) to comprise “non-woven fabric made from nylon, vinylon, etc., lints, papers, polyvinyl chloride film, polyurethane film, ethylene-vinyl acetate copolymer film, or other synthetic polymer films, which are flexible.” None of these materials are water-soluble or water-erodable; indeed Kawata makes clear that it is desirable to coat materials that even have marginal water solubility (e.g. papers) to reduce their water solubility. *Neither of the documents cited by the Examiner recites a*

*device that is water-erodable in its entirety, whereas the flexible adherent film of the present invention is explicitly stated to be water-erodable.*

Kawata further states (column 2, lines 29-31) that materials having poor water-resistance such as paper may be coated with a protecting coating layer. Thus, the combination of references does not teach or suggest the claimed invention but instead lead away from it.

Therefore, Applicants again respectfully assert that the Examiner has not properly made a case for rejection on the basis of obviousness and requests that the application properly be allowed to proceed to issue as a patent.

#### Double Patenting

Claims 19-22, 24 and 34-42 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5-6, 15-18 and 33-34 of copending Application No. 09/069,703.

Applicants traverse the provisional rejection and, to the extent that the rejection is maintained against the claims as amended herein, do not admit that claims 19-22, 24 and 34-42 are obvious over copending Application No. 09/069,703, and request withdrawal of the rejection.

As the rejection is provisional, and neither this patent application nor Application No. 09/069,703 has yet matured into a patent, Applicants will file any necessary Terminal Disclaimer when the first of these two applications is allowed to issue as a patent.

**CONCLUSION**

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612) 373-6941 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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By their Representatives,

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Date Aug 10, 2006

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**CERTIFICATE UNDER 37 CFR 1.8:** The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to Mail Stop AF, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 10<sup>th</sup> day of August 2006.

Name

Signature